510(k) SUMMARY

NOV 1 9 2002

Device: Cervive Anterior Cervical Plating System

Date: 08/22/02

Applicant's name: Corin USA
10500 University Center Drive, Suite 190
Tampa, FL 33612

Phone: (813) 977-4469
Fax: (813) 979-0042

Contact person: Joel Batts, Regulatory Affairs Manager

Classification name: Appliance, fixation, spinal intervertebral body

Product codes: 87KWQ

C.F.R. section: 21.888.3060

Device class: II

Classification panel: Orthopedic

Indications for use

The Cervive Anterior Cervical Plating System is indicated for use in temporarily stabilizing the cervical spine during the development of solid spinal fusion in patients with degenerative disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), primary and metastatic malignant tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, and/or spinal cord stenosis.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Device description

The Cervive Anterior Cervical Plating System includes plates and expanding screws, both of which are manufactured from titanium alloy ($TiAl_6V_4$) that conforms to BS 7252 Part 3 (ISO 5832-3) Metallic Materials for Surgical Implants – specifications for wrought $TiAl_6V_4$.

The plates range in length and number of holes for screw placement (see heading "Devices to be cleared in this submission" for a complete range of sizes/hole options). The expanding screws are offered in 13, 15 and 16mm lengths. Each screw provides monocortical fixation and consists of two components: the expanding screw and the conus (inner screw).

Substantial equivalence basis

The sponsor claims substantial equivalence (SE) of the Cervive Anterior Cervical Plating System to the previously approved Synthes Cervical Spine Locking Plate (K945700) and Blackstone Anterior Cervical Plate (K974885).

Mechanical testing has been carried out in accordance with ASTM 1717-96. Protocols and reports from this testing are provided in Section 9.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 9 2002

Mr. Joel Batts
Regulatory Affairs Manager
Corin USA
10500 University Center Drive, Suite 190
Tampa, Florida 33612

Re: K022798
Trade Name: Cervive Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 22, 2002
Received: August 23, 2002

Dear Mr. Batts:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022798

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

(Optional Format 3-10-98)

(Posted July 1, 1998) 510(k) Number K022798